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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,069	01/18/2006	Kazuyuki Oku	OKU 12	3696

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EXAMINER
ISSAC, ROY P

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,069	OKU ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP04/09809, filed 07/09/2004 and claims priority under 35 U.S.C §119 (a)-(d) and 365(c) to foreign application Japan 2003276602 filed 07/18/2003. A certified copy of foreign priority application in Japanese is received. A translation of the PCT application is received, but not of the foreign application.

Applicants' preliminary amendment filed 01/18/2006 in which claims 2-13 were amended and claim 14 was newly added is acknowledged. Claims 1-14 are currently pending are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation, "derivative" in these claims render claims herein indefinite. The recitations, "derivative" of the compounds are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivative" of compounds herein. One of ordinary skill in the art would clearly recognize that the recitations "{→6)-α-D-

glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof" as well as derivatives of the classes of compounds listed in claims 6 and 8-9 would read on any those compounds having any widely varying groups that possibly substitute the compounds.

Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivatives" of compounds herein encompassed thereby.

Claims 3 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of the phrase "delicious taste imparting seasoning" is not clearly defined in the specification and one of skill in the art will not know which taste imparting seasoning substances or compounds are delicious. As such, one of skill in the art would not be apprised of the metes and bounds of the claims herein.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of the phrase "substances having a mineral absorption promoting action" is not clearly defined in the specification and one of skill in the art will not know which substances will have mineral absorption promoting action. As such, one of skill in the art would not be apprised of the metes and bounds of the claims herein.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites "0.1% by weight or more" in reference to the amount of cyclic tetrasaccharide. The lack of an upper limit renders the claim indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 9-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-16 of copending Application No. 10/551,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '765 application claims a lipid-regulating agent comprising a cyclic tetrasaccharide represented by the formula {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or its saccharide-derivative(s) as an effective ingredient, and the instant application claims an accelerator for mineral absorption, which comprises an effective ingredient cyclic tetrasaccharide represented by {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof. Note that, the recitations "an accelerator for mineral absorption", "as an agent for strengthening bone", "as an agent for lowering foreign taste and/or foreign smell", "used as an agent for strengthening calcium-containing tissue" and "a lipid-regulating agent" are considered intended uses of the compositions claimed. Note that it is well settled that "intended use" of a composition or product, e.g., "as an agent for strengthening bone", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Thus, claim 1-5 and 9-14 are deemed anticipated by claims 1-16 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8 of copending Application No. 10/495,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '975 application claims compounds and composition comprising cyclic tetrasaccharide of claim 1. Thus, claim 1 is deemed anticipated by claims 1-3 and 8 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubolta et. al. (WO 01/90338, Publication Date 11/29/2001; PTO-892;). English Equivalent, U.S. Patent No. 7,192,746 is used *in lieu* of translation.

Kubolta et. al. discloses the synthesis of the cyclotetrasaccharide, cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}. (Abstract, Example A-1 to A-5, Columns 55-58). Kubolta further discloses a composition comprising said cyclic tetrasacchirde, (100 parts by weight), mineral, sodium chloride and potassium chloride, magnesium sulfate. (Example B-18, Column 65, lines 20-40). Kubolta further discloses sodium L-ascorbate, vitamin E and trehalose in composition comprising cyclic tetrasaccharide. (Example B-18, Column 65, lines 20-40). Kubolta further discloses several examples of compositions comprising said cyclostetrasaccharide and one or more of the ingredients of claims 2-14 herein. (Examples B1-B25; Columns 60-68). Note that, the recitations "an accelerator for mineral absorption", "as an agent for strengthening bone", "as an agent for lowering foreign taste and/or foreign smell", "used as an agent for strengthening calcium-containing tissue" and "a lipid-regulating agent" are considered intended uses of the compositions claimed. As discussed above, "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed.

As such, claims 1-6 and 8-14 are deemed anticipated by Kubolta et. al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kubolta et. al.

The disclosure of Kubolta et. al. is dicussed above.

Kubolta et. al. does not exemplify the use of polyphenols in the disclosed compositions.

Kubolta e.t la. discloses the use of flavonoid pigments, such as sisonine, safforl yellow, rutin and quecetin as well as flavin pigments such as riboflavin in. (Column 18, lines 63-68). The flavonoids disclosed are suggested as dyes useable in the invention. (Column 18, lines 45-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a flavonoid with a composition comprising the cyclic tetrasaccharide, cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and a mineral because Kubolta et. al. discloses compositions comprising said cyclic tetrasaccharide and minerals and broadly discloses flavanoids in particular isonine, safforl yellow, rutin, quecetin and riboflavin as dyes useful in compositions disclosed therein.

One of ordinary skill in the art would have been motivated to make compositions comprising cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, a mineral and a flavonoid because Kubolta et. al. discloses compositions comprising said cyclic tetrasaccharide and minerals and suggests flavonoids as useful as dye material for compositions therein. Furthermore, it is considered well within the basic skills of one ordinary skill in the art to add flavonoids as dyes and food additives.

Therefore, one of ordinary skill in the art would have reasonably expected that the addition of flavonoids to a compsotion comprising cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, a mineral would have had beneficial effects.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/26/07

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